APR 1 2 2001

K010926

R-dental Dentalerzeugnisse GmbH
Werk Winterhuder Weg 88 D-22085 Hamburg Telefon 0 40 / 22 75 76 17 Fax 0 40 / 22 75 76 18
Zertifiziert nach DIN EN ISO 9001 / DIN EN 46001 und EG-Richtlinie 93/42/EWG Anhang II (MEDCERT 0482)

In Kooperation mit
ORAL-PREVENT
DIE INTELLIGENTE PROPHYLAXE

10. 510(k) Summary or Statement

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:
R-dental Dentalerzeugnisse GmbH
Winterhuder Weg 88
D-22085 HAMBURG
Germany

Contact person: Dr. Andreas Sprafke
Tel.: 0049-40-22 75 76 17
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E-Mail: info@r-dental.com
Internet: www.r-dental.com

Date summary prepared: March 15th, 2001

Classification name: Material, Impression
Regulation number: 872.3660
Proprietary name (brand name): R-SI-LINE METAL-BITE
Common or Usual name: Bite registration material, dental impression material

Device description: R-SI-LINE METAL-BITE is a hard and fast A silicone and can be used for bite registrations. It can be additionally used for a powderfree optical registration of occlusal data for CAD/CAM/CIM systems.

Indication for use: The purpose of R-SI-LINE METAL-BITE is making bite registrations. It can be additionally used for a powderfree optical registration of occlusal data for CAD/CAM/CIM systems.

Substantial equivalence: The chemical composition and indication of R-SI-LINE METAL-BITE is substantially equivalent to the brand KwikkModel (R-dental) and BLU-MOUSSE (Parkell, Farmingdale, NY 11735).

Dr. Andreas Sprafke, President,
Regulatory Compliance Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2001

Mr. Andeas Sprafke
President
R-Dental Dentalerzeugnisse GMBH
Winterhuder WEG 88
D-22085 Hamburg
GERMANY

Re: K010926
Trade Name: R-SI-Line Metal-Bite
Regulatory Class: II
Product Code: ELW
Dated: March 15, 2001
Received: March 27, 2001

Dear Mr. Sprafke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucenta/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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9. Statement of Indication for Use

Statement

510(k) Number (if known): -

Device name: **R-SI-LINE METAL-BITE**

Indication for Use (see appendix 2):

powderfree

R-SI-LINE METAL-BITE is a bite registration material based on vinylpolysiloxane base (A silicone). It can be additonally used for a optical registration of occlusal data for CAD/CAM/CIM systems.

MSDS (see appendix 3):

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Pamela D. Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010926

Prescription Use: or Over-The-Counter Use